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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
09/450,999	11/29/99	PORTER	3 CELL-0086

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FRANCIS A PAINTIN ESO
WOODCOCK WASEBURN KURTZ
MACKIEWICZ & NORRIS
ONE LIBERTY PLACE-46TH FLOOR
PHILADELPHIA PA 19103

EXAMINER

MCKENZIE, T

ART UNIT

PAPER NUMBER

1624

DATE MAILED:

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Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

Office Action Summary	Application No.	Applicant(s)
	09/450,999	PORTER ET AL.
	Examiner	Art Unit
	Thomas C McKenzie, Ph.D.	1624

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1) Responsive to communication(s) filed on 27 April 2001.

2a) This action is FINAL. 2b) This action is non-final.

3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4) Claim(s) 2-22 is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5) Claim(s) _____ is/are allowed.

6) Claim(s) 2-22 is/are rejected.

7) Claim(s) _____ is/are objected to.

8) Claims _____ are subject to restriction and/or election requirement.

Application Papers

9) The specification is objected to by the Examiner.

10) The drawing(s) filed on _____ is/are objected to by the Examiner.

11) The proposed drawing correction filed on _____ is: a) approved b) disapproved.

12) The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

13) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a) All b) Some * c) None of:

1. Certified copies of the priority documents have been received.
2. Certified copies of the priority documents have been received in Application No. _____.
3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14) Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

Attachment(s)

15) Notice of References Cited (PTO-892) 18) Interview Summary (PTO-413) Paper No(s). _____.

16) Notice of Draftsperson's Patent Drawing Review (PTO-948) 19) Notice of Informal Patent Application (PTO-152)

17) Information Disclosure Statement(s) (PTO-1449) Paper No(s) 15&16&18. 20) Other: _____.

DETAILED ACTION

1. This action is in response to amendments filed 9/25/01. There are twenty-one pending claims. Claims 2-14 and 16 are compound claims. Claim 15 is a composition claim. Claims 17-22 are use claims. This is the third action on the merits. Claims 2-22 were previously rejected. Applicants have amended claim 16. The application concerns β -amidobenzenepropanoic acid compounds. This action is not made final because additional prior art has been found which anticipates Applicants' claims.

Response to Amendment

2. Applicants' amendment to claim 16, listing the twenty "heteroatom containing groups" overcomes the indefiniteness rejection made in point #6 of the previous office action. Applicants' amendment to claim 16, spelling out which heteroatoms are to be included in their claims to "heteroatoms" overcomes the indefiniteness rejection made in point #8 of the previous office action. Applicants' specification contains on page 22, lines 8-11 a specific and, with the exception of MS, a credible assertion of utility. Thus, the utility rejection made in point #12 of the previous office action is withdrawn. Applicants' provisos, in the last ten lines of claim 16 overcome all the anticipation rejections made in points #13-16 of the previous office action. None of the art employed in these rejections teaches

biological activity of the disclosed compounds. Thus, none of this art makes obvious Applicants' compounds. Please see point #5 below.

Claim Rejections - 35 USC § 112

3. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action. Claims 17-20 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for treating diseases, does not reasonably provide enablement for preventing any diseases. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to use the invention commensurate in scope with these claims. The only established prophylactics are vaccines, not the β -amidobenzenepropanoic acid compounds of the present application.

Applicants have argued that the last "Office Action presents no such technical reasoning to support the opinion". Applicants cite Abraham, *J. Clin. Invest.* in support of the claim to prevention "of any clinical symptoms". This is not persuasive. Applicants' claims read on the prevention of any claimed disease not just the sheep model of asthma used by Abraham. Prevention of asthma would mean prevention of development of the disease in an asymptomatic individual. The model cited by Applicants is connected to an asthmatic episode in a patient

who has developed the disease. Applicants' claims would read on prevention of arthritis, MS, inflammatory bowel disease etc. Since no compound has shown the ability to inhibit the development of these diseases in an asymptomatic individual and no compound which works by a cell adhesion mechanism has ever shown clinical efficacy in treatment of these diseases in humans it is beyond medical understanding that a physician would know how to use Applicants compounds to prevent these diseases.

4. Claims 17 and 18 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for treating the diseases tabulated in claim 18, does not reasonably provide enablement for treatment of multiple sclerosis. Noseworthy's (Nature) review on treatment of MS lists "Adhesion-molecule signaling" in Table 2 on page A45 as a "Possible future therapeutic strategies". Thus, implying that such mechanistic approaches like Applicants have not demonstrated efficacy in MS. Noseworthy's (Curr. Opin. Neurology) second recent review on MS treatment describes adhesion molecules and MS in the paragraph spanning both column of page 289 and the following paragraph. An antibody to a4 integrins, which would have the same mechanism of action as Applicants' claimed molecules, is reported as "still under investigation." Again, implying that such approaches, as Applicants' have not demonstrated efficacy in

MS. Attention is drawn to the final two sentences of this passage “[t]his approach has also led to severe side effects ...”.

Applicants have argued that Yednock, *Nature*, has shown that antibodies to VLA-4 have shown activity in an MS animal model. This is not pervasive for two reasons. Firstly, Applicants' compounds have not shown activity in the animal model, nor have any small molecule cell-adhesion inhibitors. Secondly, there is no evidence of record demonstrating any correlation between the model of Yednock and clinical efficacy in humans. Case law is clear on this point. In an unpredictable art, such as MS therapy, models may be used for enablement only if there is a well-established correlation between the assay and clinical efficacy.

The issue in *Ex parte Balzarini* 21 USPQ2d 1892 concerned HIV treatment and the Board of Patent Appeals and Interferences wrote “While the *in vitro* testing performed on these anti-viral compounds appears to be useful as a screening tool in order to determine which of these anti-viral compounds are candidates for further testing to determine if they possess *in vivo* utility, the *in vitro* tests were not predictive of *in vivo* efficacy.”

The issue in *Fujikawa v. Wattanasin* 39 USPQ2d 1895 was adequacy of *in vitro* testing of inhibitors of cholesterol biosynthesis and U.S. Court of Appeals Federal Circuit wrote “*in vitro* results, in combination with a known correlation between such *in vitro* results and *in vivo* activity, may be sufficient to establish practical utility.” Such a correlation does not exist in the art of MS therapy.

In a peripheral issue involving assaying insulin-like growth factor-I ("IGF-I") in *Genentech Inc. v. Chiron Corp.* 55 USPQ2d 1636, U.S. Court of Appeals Federal Circuit wrote "by the critical date, ... [s]pecific binding in an RRA was known by those skilled in the art to be reasonably correlated with the *in vivo* biological activity of IGF-I."

In a case which is factually similar to the present application in that no biological testing data from Applicants' compounds was revealed, *Ex parte Bhide* 42 USPQ2d 1441, the Board of Patent Appeals and Interferences wrote "While *in vitro* or *in vivo* tests would not be the only possible way to overcome our basis for questioning applicants' utility, *in vitro* or *in vivo* tests certainly would provide relevant evidence". The issue in the present case is case is not the utility of applicants' compounds, which was at issue in *Ex parte Bhide* 42 USPQ2d 1441, but rather the narrower issue of enablement for claims drawn to the treatment of MS. Since such a claim is inherently not credible, the standard of proof required for such an assertion must be high.

In a case concerning a DNA sequence encoding a mature human IL-3 protein, *Ex parte Anderson* 30 USPQ2d 1866, the Board of Patent Appeals and Interferences wrote in passing "We question whether one skilled in the art would accept appellants' *in vitro* test as predictive of *in vivo* results and whether one skilled in the art would know how to use the Pro (8) protein made. ... Should the claims of this application be prosecuted further in a continuing application we urge the examiner to consider the enablement and utility aspects of patentability."

In an anti-tumor application, *Ex parte Aggarwal* 23 USPQ2d 1334, the Board of Patent Appeals and Interferences wrote "there is considerable doubt that those skilled in the art would be willing to accept appellants' *in vitro* tests and *in vivo* tests as established models predictive of utility against tumors in humans. See *In re Jolles*, 628 F.2d 1322, 206 USPQ 885 The examiner had more than adequate reason to doubt the objective truth of the broad statement of utility set forth in appellants' specification."

In the most definitive finding on the issue of the adequacy of *in vitro* assays for clinical claims, *Ex parte Stevens* 16 USPQ2d 1379 the Board of Patent Appeals and Interferences wrote "The examiner's position is based on the supposition that the facts described above evidence a *prima facie* case of nonenablement with regard to the disclosed utility in light of all the applicable legal precedents. Where as here, the disclosed utility is the treatment of cancer, we agree with this supposition. The examiner has cited *Ex parte Busse*, 1 USPQ2d 1908. In that case, the Board of Patent Appeals and Interferences reviewed the relevant prior decisions of its reviewing court. We shall not repeat those citations here. Suffice it to say that in every cited case the narrow issue involved was whether or not the evidence of record was based on *in vivo* or *in vitro* studies which were generally recognized by those of ordinary skill in the art as being reasonably predictive of success in the practical utility under consideration, i.e., human or, at least, mammalian therapy."

In a vaccine case, *Ex parte Maas* 14 USPQ2d 1762, the Board of Patent Appeals and Interferences wrote "First, although appellants' specification describes certain *in vitro* experiments, there is no correlation on this record between *in vitro* experiments and a practical utility in currently available form for humans or animals. It is not enough to rely on *in vitro* studies where, as here, a person having ordinary skill in the art has no basis for perceiving those studies as constituting recognized screening procedures with clear relevance to utility in humans or animals. The burden is on appellants to establish the significance of the *in vitro* experiments set forth in their specification."

5. Claims 2-22 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. The proviso in the last ten lines of claim 16 lacks description. Nowhere in the specification is such a relationship linking the description among radicals Ar¹, r, L¹, Ar², R¹ and R³ described. Such a negative limitation requires description. In *Ex parte Grasselli, et al.* 231 USPQ 393, decided June 30, 1983, the U.S. Patent and Trademark Office, Board of Patent Appeals and Interferences said: "we agree with the examiner's position of record that the negative limitations recited in the present

claims, which did not appear in the specification as filed, introduce new concepts and violate the description requirement of the first paragraph of 35 U.S.C. 112.” “It might be added that the express exclusion of certain elements implies the permissible inclusion of all other elements not so expressly excluded. This clearly illustrates that such negative limitations do, in fact, introduce new concepts.”

6. Claims 2-22 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. In the last line of both claim 14 and claim 16, Applicants have the word “solvates”. This reads on an unlimited and undefined number of solvent complexes with Applicants’ claimed compounds. What solvents are envisioned? The Examiner suggests deleting the term.

Applicants have argued that “to specifically enumerate such solvents .. would serve to needlessly limit Applicants invention.” This is not persuasive on two grounds. Such a long list of hypothetical solvates would certainly raise issues of enablement and new matter. Secondly, the Examiner in the previous action raised a question regarding the structures of the claimed molecules. Do Applicants posses a method of terming in any given solvent will form a solvate the billions of claimed compounds? How much solvent must be present in the crystal lattice to qualify as a “solvate”? How tightly must the solvent molecule be bound to

qualify? If applicants can not answer the question how then is the public to determine intended scope?

7. Claims 2-13 and 15-22 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Applicants repeatedly claim "optionally substituted" in reference to their aliphatic, heterocycloaliphatic etc groups. This is indefinite because we do not know what these substituents are or where there are to be placed. The Examiner suggests that these substituent groups be spelled out in the claims so that we know what Applicants intend. For example, in the lines spanning pages 3 and 4 of the amendments Applicants do definitely claim what they intend for R^b. In lines 8-22 of page 7, Applications use open language to indicate possible aromatic or heteroaromatic substituents. In the passage spanning line 14, page 13 to line 4, page 14 there is a second, conflicting, open language indication of possible aromatic or heteroaromatic substituents. Possible aliphatic substituents are suggested in lines 27-34 of page 10. In each case, since open language is used, what other substituents are being claimed.

Applicants argue that such language "must be read in view of the specification", "that the biological activity would be expected to be maintained despite the specific nature of the substituent groups", and "this would be

immediately apparent to one of ordinary skill in the art". This is not persuasive for three reasons. Firstly, there is conflicting definitions for one of the groups. Secondly, the language in the specification, which defines the substituents, is open, thus the metes and bounds of Applicants' claimed substituents is uncertain. Thirdly, Hawley (The Condensed Chemical Dictionary) defines substituent as "atom or radical ... ". Thus, Applicants' claimed substituent can be any monovalent collection of atoms of any size and complexity.

8. Claims 2-13 and 15-22 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. In claim 16, Applicants repeatedly refer to "heteroaliphatic", "cycloaliphatic", and "polycycloaliphatic" and "hetero polycycloaliphatic". These are all improper. To quote from Hawley (The Condensed Chemical Dictionary) "aliphatic ... characterized by straight- or branched-chain arrangement of the constituent carbon atoms." An aliphatic group may be saturated or unsaturated. An aliphatic group may not contain rings or hetero atoms. Applicants' terms "heteroaliphatic", "cycloaliphatic", and "polycycloaliphatic" and "hetero polycycloaliphatic" are not recognized in the art of organic chemistry and are oxymorons. Thus, we do not know what Applicants intend by these unique terms since the prefixes conflict with the stem word

aliphatic. The Examiner suggests “alicyclic” and “heterocyclic” if that is what they intend.

Applicants have argued that “one of ordinary skill in the art would understand.” This is not persuasive. Aliphatic has a specific art-recognized meaning which is contradictory to Applicants’ meaning. Applicants’ provide no guidance in the specification as to which groups they intend. While applicant may be his or her own lexicographer, a term in a claim may not be given a meaning repugnant to the usual meaning of that term. See *In re Hill*, 161 F.2d 367, 73 USPQ 482 (CCPA 1947).

9. Claims 2-13 and 15-22 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. In amended claim 16, fifth line, page 5, Applicants have amended the word “carboxylic acid”, to “carboxylic acid (CO₂H)”. This does clarify what they intended by “carboxylic acid”. Unfortunately, the phrase “ester group or amide group” is indefinite. An ester group is the product of the reaction between an acid and an alcohol. An amide group is the product of the reaction between an acid and an amine. Does this embrace the acids of sulfur and phosphorus? How are the ester and amide groups attached? Is it through the central atom of the acid group or through some other

carbon atom? What is the specific stem, i. e. if ester is $RC(O)O$, what is R? Are there any limitations upon the alcohols and amines used to form these groups? The Examiner suggests 'carboxyl, carbonylalkoxy, or carboxyamido'.

10. Claim 17 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. The phrase "a disease or disorder in a mammal in which the extravascation of leukocytes plays a role" is indefinite. Applicants have argued that the passage on page 22, lines 8-11 exemplifies what diseases they intend. This is not persuasive. The claim provides for the use of claimed compounds, but the claim does not set forth any steps involved in determining which are the "a disease or disorder in a mammal in which the extravascation of leukocytes plays a role". It is unclear which diseases are "a disease or disorder in a mammal in which the extravascation of leukocytes plays a role". Determining whether a given disease has any such mechanism will involve undue experimentation. Suppose that a given drug, which controls extravascation of leukocytes *in vitro*, when administered to a patient with a certain disease, does not produce a favorable response. One can not conclude that specific disease does not fall within this claim. Keep in mind that:

A. It may be that the next patient will respond. No pharmaceutical has 100% efficacy. What success rate is required to conclude our drug is a treatment? Thus, how many patients need to be treated? If "successful treatment" is what is intended, what criterion is to be used? If one person in 10 responds to a given drug, does that mean that the disease is treatable? One in 100? 1,000? 10,000? Will the standard vary depending on the current therapy for the disease?

B. It may be that the wrong dosage or dosage regimen was employed. Drugs with similar chemical structures can have markedly different pharmacokinetics and metabolic fates. It is quite common for pharmaceuticals to work and/or be safe at one dosage, but not at another that is significantly higher or lower. Furthermore, the dosage regimen may be vital --- should the drug be given e.g. once a day, or four times in divided dosages? The optimum route of administration can not be predicted in advance. Should our drug be given as a bolus *iv* or in a time release *po* formulation. Thus, how many dosages and dosage regimens must be tried before one is certain that our drug is not a treatment for this specific disease?

C. It may be that our specific drug, while active *in vitro*, simply is not potent enough or produces such low concentrations in the blood that it is not an effective treatment of the specific disease. Perhaps a structurally related drug is potent

enough or produces high enough blood concentrations to treat the disease in question, so that the first drug really does fall within the claim. Thus, how many different structurally related controllers of the extravascation of leukocytes must be tried before one concludes that a specific compound does not fall within the claim?

D. Conversely, if the disease responds to our second drug but not to the first, both of whom controls extravascation of leukocytes *in vitro*, can one really conclude that the disease falls within the claim? It may be that the first compound result is giving the accurate answer, and that the success of second compound arises from some other unknown property which the second drug is capable. It is common for a drug, particularly in the CNS, to work by many mechanisms. The history of psychopharmacology is filled with drugs, which were claimed to be a pure receptor XYX agonist or antagonist, but upon further experimentation shown to effect a variety of biological targets. In fact, the development of a drug for a specific disease and the determination of its biological site of action usually precede linking that site of action with the disease. Thus, when mixed results are obtained, how many more drugs need be tested?

E. Suppose that our drug is an effective treatment of the disease of interest, but only when combined with some totally different drug. There are for example, agents in antiviral and anticancer chemotherapy which are not themselves

effective, but are effective treatments when the agents are combined with something else.

Consequently, determining the true scope of the claim will involve extensive and potentially inconclusive research. Without it, one skilled in the art cannot determine the actual scope of the claim. Hence, the claim is indefinite.

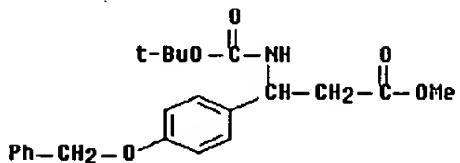
Claim Rejections - 35 USC § 102

11. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

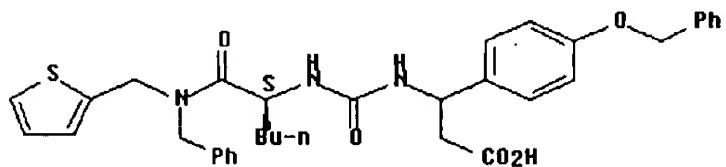
A person shall be entitled to a patent unless –

- (a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.
- (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.
- (e) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, or on an international application by another who has fulfilled the requirements of paragraphs (1), (2), and (4) of section 371(c) of this title before the invention thereof by the applicant for patent.

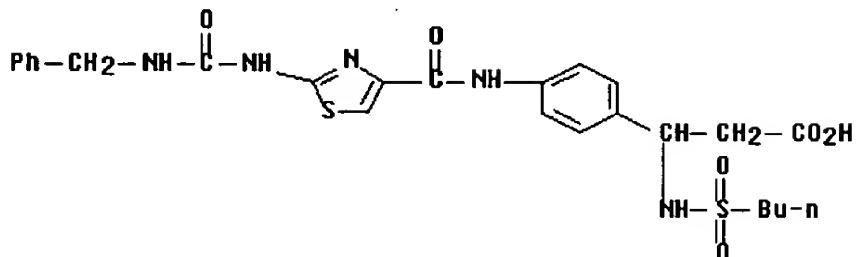
Claims 3, 4, 7-10, and 16 are rejected under 35 U.S.C. 102(b) as being anticipated by Kato (Tetrahedron Lett.). There are three compounds in this reference which anticipate Applicants claims with Ar^1 = phenyl, $r = 1$, $L^1 = -O-$, $Ar^2 = 1,4$ -phenylene, $R^1 = NHC(O)C(CH_3)_3$, $R^a = R^{a'} =$ hydrogen, and $R = CO_2$ methyl. The compounds are number 5 and 6 in the reference and are found in the scheme on the left side of page 6465.



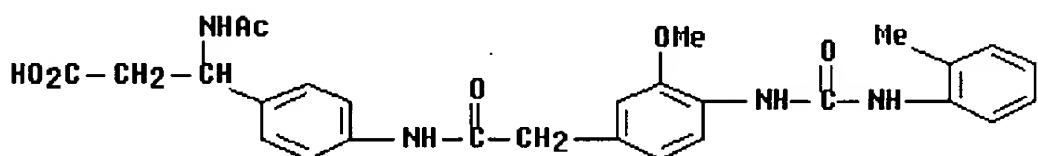
12. Claims 2-8, and 16-22 are rejected under 35 U.S.C. 102(e) as being anticipated by Scott ('773). There is one compound in this reference which anticipate Applicants claims claims with Ar¹ = phenyl, r = 1, L¹ = -O-, Ar² = 1,4-phenylene, R¹ = [[(1S)-1-[[[phenylmethyl)(2-thienylmethyl)amino]carbonyl]pentyl]amino]carbonyl, R^a = R^{a'} = hydrogen, and R = CO₂H.



13. Claims 2-8, and 16-22 are rejected under 35 U.S.C. 102(e) as being anticipated by Alig ('282). There are five compounds in this reference which anticipate Applicants claims claims with Ar¹ = 4-thiazolyl substituted by 2-[[[phenylmethyl)amino]carbonyl]amino], r = 0, L¹ = -CONH-, Ar² = 1,4-phenylene, R¹ = (butylsulfonyl)amino, R^a = R^{a'} = hydrogen, and R = CO₂H.



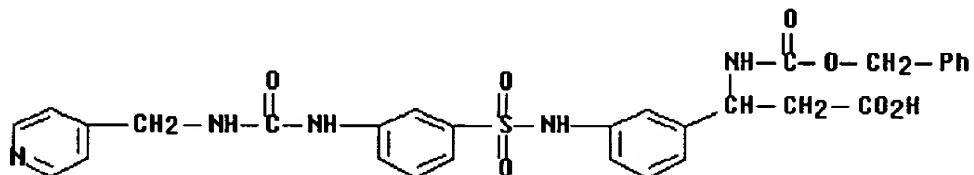
14. Claims 2-8, and 16-22 are rejected under 35 U.S.C. 102(a) as being anticipated by Astles (WO 99/23063 A1). There are forty-seven compounds in this reference which anticipate Applicants claims. The one shown below has Ar^1 = phenyl substituted by [3-methoxy-4-[[[(2-methylphenyl)amino]carbonyl]amino]phenyl, $r = 1$, $\text{L}^1 = -\text{CONH}-$, $\text{Ar}^2 = 1,4\text{-phenylene}$, $\text{R}^1 = \text{NHC(O)CH}_3$, $\text{R}^a = \text{R}^{a'} =$ hydrogen, and $\text{R} = \text{CO}_2\text{H}$. It is found in Example 3, page 66, lines 15-19. See also claims 26-34. Should this reference issue as a US patent, it would be a 102(b) reference against Applicants' claims.



Interference

15. Applicants' attention is drawn to Schoop (WO 00/41469 A1). There are fifty-eight compounds disclosed in this reference which overlap Applicants claims.

While the publication and filing dates of Schoop (WO 00/41469 A1) are not sufficient to anticipate Applicants' claims, any US Patent which issue from Schoop (WO 00/41469 A1) could provoke an interference with Applicants' claims.



Conclusion

16. Please direct any inquiry concerning this communication or earlier communications from the Examiner to Thomas C McKenzie, Ph. D. whose telephone number is (703) 308-9806. The Examiner is available from 8:30 to 5:30, Monday through Friday. If attempts to reach the Examiner by telephone are unsuccessful, the Examiner's supervisor, Mukund Shah can be reached on (703) 308-4716. Please direct general inquiries or any inquiry relating to the status of this application to the receptionist whose telephone number is (703) 308-1235.


Richard Raymond
Primary Patent Examiner
Art Unit 1624


TCMcK
May 29, 2001